by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP–300491] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 8, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.431, paragraph (b) is amended by revising the introductory text, the column headings to the table, in the third column of the table by changing ''July 31, 1998'' to read ''7/31/98'' and by adding an entry for canola to the table.

§ 180.431 Clopyralid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide clopyralid in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Canola	3	7/31/98
* *	*	* *

* * * * *

[FR Doc. 97–12913 Filed 5–15–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300492; FRL–5718–4]

RIN 2070–AB78

Pyridaben; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances with an expiration date of May 31, 2001 for residues of the pesticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in or on the food commodities apples, wet apple pomace, pears, citrus, citrus oil, almonds, almond hulls, meat, milk and fat. A petition was submitted by BASF Corporation to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance. These tolerances will expire and are revoked on May 31, 2001.

DATES: This regulation becomes effective May 16, 1997. Objections and

requests for hearings must be received by EPA on or before July 15, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300492], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300492], should be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division, (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM#2, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: OPP-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300492]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Marion Johnson Jr. Product Manager (PM) 10, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 210, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703) 305–6788, e-mail: johnson.marion@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, in the March 12, 1997 **Federal Register** (62 FR 11450)(FRL–5592–7), which announced that BASF Corporation had submitted pesticide petitions (PP) 5F4543 (on citrus), and 6F4651 (on apples), 6F4741 (on pears), and 6F4721 (on almonds). Pesticide petitions 5F4543, 6F4651, 6F4741 and 6F4721 requested that the Administrator, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C 346a, amend 40 CFR part 180 to establish tolerances for residues of the pesticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one; EPA Chemical No. 129105; CAS No. 96489–71–3] in or on the food commodities: apples, wet apple pomace, pears, citrus, dried citrus pulp, citrus oil, almonds, and almond hulls. The proposed tolerance levels for pyridaben and its metabolites are:

Commodity	Parts per million
Almond hulls	4.0
Almonds	0.05
Apple pomace, wet	1.0
Apples	0.6
Citrus	0.5
Citrus oil	10
Citrus pulp, dried	1.5
Milk	0.01
Fat	0.05
Meat	0.05
Meat by-products	0.05
Pears	0.75

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Pub. L. 104–170, BASF included in the notice of filing a summary of the petitions and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. The summary of the petitions prepared by the petitioner contained conclusions and assessments to support its conclusions that the petition complied with FQPA elements set forth in section 408(d)(3) of the FFDCA.

There were no comments received in response to the notice of filing.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., as amended by the Food Quality Protection Act of 1996, (FQPA) Pub. L. 104–170) authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on food commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq*.).

Section 408 was substantially amended by the FQPA. Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

II. Risk Assessment and Statutory Findings — Background

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once the studies have been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime

will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. An aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm. For threshold effects other than those assessed under the RfD, EPA generally calculates a margin of exposure (MOE). The MOE is a measure of how close the exposure comes to the NOEL. The NOEL is selected from a study of appropriate duration and route of exposure. The MOE is the NOEL from the selected study divided by exposure. MOEs greater than 100 are generally considered to show a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water and exposures resulting from indoor and outdoor residential uses. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with sections 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology database for pyridaben in its evaluation of application for registration on citrus, apples, pears and almonds. EPA has sufficient data to assess the hazards of pyridaben and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting time-limited tolerances for residues of pyridaben on apples at 0.6 ppm, wet apple pomace at 1.0 ppm, pears at 0.75 ppm, citrus at 0.5 ppm, dried citrus pulp at 1.5 ppm, citrus oil at 10.0 ppm, milk at 0.01 ppm, meat at 0.05 ppm, meat by-products at 0.05 ppm, fat at 0.05 ppm, almonds at 0.05 ppm, almond hulls at 4.0 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing these tolerances follows.

III. Toxicology Database

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyridaben are discussed below.

1. A battery of acute toxicity studies placing technical pyridaben in toxicity category II for acute oral toxicity and category III and IV for the remaining studies.

2. Pyridaben was administered in the diet to CD rats at dosages of 0, 30, 65, 155 and 350 ppm for 13 weeks. The NOEL was determined to be 65 ppm (4.94 mg/kg/day) for males; 30 ppm (2.64 mg/kg/day) for females. The lowest observed effect level (LOEL) was determined to be 155 ppm (11.55 mg/kg/day) for males based on reduced body weight gain, food consumption, food efficiency and altered clinical pathology parameters; 65 ppm (5.53 mg/kg/day) for females based on reduced body weight gain and food efficiency.

3. In a 13 week feeding study in dogs, Pyridaben was administered in capsules to beagle dogs at dosages of 0, 0.5, 1.0, 4.0 or 16.0 mg/kg/day. The NOEL was 1.0 mg/kg/day for males and females and the LOEL was 4.0 mg/kg/day for males and females based on an increased incidence of clinical signs and decreased body weight gain.

4. In a 21 day dermal study, rats received repeated topical applications of pyridaben to about 10% of the body surface area at dosages of 30, 100, 300 and 1,000 mg/kg for 21 days produced body weight decreases in the 300 mg/kg/day females and in the 1,000 mg/kg/day males and females. The NOEL was 100 mg/kg/day and the LOEL was 300 mg/kg/day based on decreased body weight gain in females.

5. In a 12–month chronic feeding study in dogs pyridaben was administered in capsules at dosages of 0, 1.0, 4.0, 16.0 or 32.0 mg/kg/day. The NOEL was determined to be < 1.0 mg/kg/day and the LOEL was ≤ 1.0 mg/kg/day based on increased incidence of clinical signs in both sexes and decreased body weight gain in females at 1.0 mg/kg/day.

6. Pyridaben was administered in capsules to beagle dogs at dosages of 0 and 0.5 mg/kg/day for 1 year. The NOEL was determined to be < 0.5 mg/kg/day for males and females and the LOEL was ≤ 0.5 mg/kg/day for males and females based on an increased incidence of clinical signs in both treated sexes and decreased weight gain in the treated females.

7. Pyridaben was administered in the diet to CD-1 mice at dosages of 0, 2.5, 8.0, 25 or 80 ppm for 78 weeks. There was no evidence of a carcinogenic effect of the chemical. The NOEL was determined to be 25 ppm (2.78 mg/kg/day) for males and females and a LOEL of 80 ppm (8.88 and 9.74 mg/kg/day for males and females, respectively). The MTD was determined to be 80 ppm for males and females based on decreased body weight gain, decreased food efficiency and changes in organ weights and histopathology (males).

8. Pyridaben was administered in the diet to groups of Wistar rats for 104 weeks at doses of 0, 4, 10, 28 or 80 ppm to assess carcinogenicity. Additional groups received doses of 0, 4, 10, 28 or

120 ppm for 104 weeks (with an interim sacrifice at 53 weeks) to assess chronic toxicity. There was no treatment-related neoplastic or non-neoplastic pathology in either phases of the study. The NOEL was determined to be 28 ppm in males (1.13 mg/kg/day) and 28 ppm (1.46 mg/kg/day) in females. The LOEL was determined to be 120 ppm (5.00 mg/kg/day) in males and 120 ppm (6.52 mg/kg/day) in females based on decreased body weight gain in males and females and decreased ALT levels in males in the chronic toxicity phase. There was no evidence of a carcinogenic effect of this chemical.

9. Pyridaben was administered to female Sprague-Dawley rats from days 6 through 15 of gestation at dosages of 0, 2.5, 5.7, 13.0 or 30.0 mg/kg/day. Maternal toxicity was evidenced by decreased body weight/body weight gain and food consumption in the 13 and 30 mg/kg/day groups. The Maternal NOEL is 4.7 mg/kg/day (82% of 5.7 mg/kg/day); The Maternal LOEL is 13.0 mg/kg/day based on decreased body weight/weight gain and food consumption during the dosing period. The Developmental NOEL is 13.0 mg/kg/day; a Developmental LOEL of 30 mg/kg/day based on decreased fetal body weight and increased incomplete ossification in selected bones.

10. A study was performed in Himalayan rabbits in which the test compound was administered to groups of female pregnant rabbits by dermal application at dose levels of 0, 70, 170, or 450 mg/kg/day from gestational days 6 to 19, inclusive. The Maternal toxicity, observed at 70 mg/kg/day, was manifested by moderate to severe skin reactions. At ''170 mg/kg/day, there was body weight loss and food consumption and moderate to severe skin reactions in 50% of the animals. In addition, the severity of skin reactions increased in a time-and dose-dependent manner. The maternal systemic NOEL is 70 mg/kg/day. Developmental toxicity observed at 450 mg/kg/day (HDT) consisted of increase in the incidence of fetuses with incompletely ossified skull. The developmental NOEL was 170 mg/kg/day.

11. New Zealand white rabbits were dosed with 0, 1.5, 5, or 15 mg/kg/day pyridaben from day 6 through 19 of gestation. Maternal toxicity was evidenced by a dose-dependent decrease in body weight gain and food consumption at al dose levels. There was also increase incidence of abortions and clinical signs (few feces) in the 15 mg/kg/day group. There was no evidence that the chemical had a developmental effect at any of the tested levels. the maternal NOEL was < 1.5 mg/kg/day and the Maternal LOEL was < 1.5 mg/kg/day based on decreases in body weight gain and food consumption at all dose levels. The developmental NOEL was > 15 mg/kg/day and the Developmental LOEL was > 15 mg/kg/day.

12. In a standard two-generation reproduction study, CD rats were administered pyridaben in the diet at doses of 0, 10, 28 or 80 ppm. There was no effect on reproductive parameters on the dose levels tested. The Parental/Systemic NOEL is 28 ppm (2.20 and 2.41 mg/kg/day for males and females, respectively). The parental/systemic LOEL is 80 ppm (6.31 and 7.82 mg/kg/day for males and females, respectively) based on decreased body weights, body weight gains and food efficiency. The reproductive NOEL is ≥ 80 ppm in males and females. The reproductive LOEL is > 80 ppm in males and females.

13. Mutagenicity studies including Ames testing, *in vitro* cytogenicity (chinese hamster lung cell), *in vivo* micronucleus assay (mouse) and DNA damage/repair (*E. coli*) showed no mutagenic activity associated with pyridaben.

14. In an acute neurotoxicity study, rats were dosed once with 0, 50, 100 and 200 mg/kg body weight (active ingredient equivalents: 44.3, 79.6, and 190 mg/kg for males and 0, 44.5, 99.7, and 190 mg/kg body weight for females). The animals were observed for mortality and clinical signs of toxicity for 14 days post-dosing. No treatment related gross or microscopic neuropathologic findings were present. The NOEL for systemic toxicity is 50 mg/kg/day in both sexes. The LOEL for systemic toxicity is 100 mg/kg in males and females based on the clinical signs of toxicity, and decreased food consumption and body weight gain. Based on the findings of this study (screening battery), the LOEL for neurobehavioral effects was established at 200 mg/kg in males (FOB findings and motor activity); no LOEL was established for females (>HDT).

15. In a subchronic neurotoxicity study pyridaben was administered to CD rats at dietary levels of 0, 30, 100, and 350 ppm (0, 2.5, 8.5 and 28.8 mg/kg/day in males and 0, 2.8, 9.3 and 31.1 mg/kg/day in females, respectively) for 13 weeks. No neuropathological effects were observed. The LOEL was established at 350 ppm (28.8 mg/kg/day in males and 31.1 mg/kg/day in females). The NOEL was established at 100 ppm (8.5 mg/kg/day in males and 9.3 mg/kg/day in females.

B. Toxicology Profile

1. *Toxicity endpoint for dietary exposure*—i. *Chronic effects.* A reference dose (RfD) has been estimated for pyridaben at 0.005 mg/kg/day based on a NOEL of 0.5 mg/kg/day (lowest dose tested) observed in a 1 year dog study for body weight gain reduction. An uncertainty factor of 100 was utilized to account for both interspecies and intraspecies variability.

ii. *Acute toxicity.* To assess acute dietary exposure, the Agency used a toxicity endpoint of 50 mg/kg/day, the NOEL for the acute oral neurotoxicity study in rats.

iii. *Carcinogenicity.* Based on the available carcinogenicity studies in two rodent species, the Agency has classified pyridaben as a Group ''E'' for carcinogenicity (no evidence of carcinogenicity). There was no evidence of carcinogenicity in an 18–month feeding study in mice and a 2–year feeding study in rats at the dose levels tested.

2. *Toxicity endpoints for non-dietary exposure*—i. *short- and intermediate-term risk.* As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern. For pyridaben, the Agency does not have a concern for a short-term or intermediate-term assessment since the available data do not indicate any evidence of significant toxicity by the dermal or inhalation routes. Therefore, a short-term or intermediate-term assessment was not required. Since there are no residential uses or exposure, a residential risk assessment is not required.

ii. *Chronic non-dietary exposure.* As part of the hazard assessment process an endpoint of concern was determined for the chronic non-dietary assessment. However, during the exposure assessment process, the exposures which would result from the use of pyridaben was determined to be of an intermittent nature. The frequency and duration of these exposures do not exhibit a chronic exposure pattern. The exposures do not occur often enough to be considered a chronic exposure i.e., a continuous exposure that occurs for at least several months. Therefore, a chronic occupational assessment was not required.

C. Aggregate Exposure

1. *Food and feed uses.* For purposes of assessing the potential chronic dietary exposure from the use of pyridaben on citrus, apples, almonds and pears, EPA has estimated aggregate exposure based on Anticipated Residue Contribution (ARC). For plant commodities, anticipated residue levels were calculated from field trials conducted at the maximum proposed

use rate and minimum pre-harvest interval (PHI), and the ratio of organosoluble residues to pyridaben residues. The ARC for processed commodities was based upon the average residue level for that commodity from field trials conducted at the maximum proposed use rate and minimum PHI, the ratio of organosoluble residues to pyridaben residues, and the concentration factor for the processed commodity. In some cases, adjustments for degradation of residues prior to analysis was taken into account. Anticipated residue levels were utilized for livestock feedstuffs to determine the dietary burden for ruminants, as well as for ruminant edible commodities. The proposed pyridaben tolerances result in an ARC that is up to 74 percent of the reference dose for the most sensitive subpopulation. The general population is 11.8 percent of the RfD.

The endpoint for acute dietary risk assessment is the NOEL (50 mg/kg/day) from an acute oral neurotoxicity study in rats. The effects at the LOEL of 100 mg/kg/day were clinical signs of toxicity, and a decrease in food consumption and body weight gain. The DRES detailed acute analysis estimates the distribution of a singe -day exposure for the overall U.S. population and certain subgroups. For acute dietary risk for the population subgroup with the highest exposure, non-nursing infants (<1 year), the estimated margin of exposure (MOE) is 1,250. The margin of exposure (MOE) is a measure of how close the high end exposure comes to the LOEL and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern. The Agency considers the acute and chronic dietary risks to be acceptable.

In conducting this exposure assessment, EPA has made conservative assumptions— 100 percent of the apples, citrus, almonds and pears will contain pyridaben residues. This will result in an overestimate of human exposure.

2. *Potable water.* The Agency does not have drinking water monitoring data available to perform a quantitative drinking water risk assessment for pyridaben at this time. Based on the available environmental fate data, conservative estimates produced by the Generic Expected Environmental Concentration (GENEEC) model and Leaching Index, environmental concentrations of pyridaben in surface water and the leaching potential of pyridaben have been derived. Pyridaben has been assessed as immobile and thus unlikely to leach to groundwater. For surface water, the GENEEC model estimates body-weight based on chronic exposure values for pyridaben to be 9.7×10^{-7} mg/kg/day for the whole U.S. population and 1.8×10^{-6} mg/kg/day for non-nursing infants (< 1 year). These values represent < 0.1% of the RfD. As GENEEC is a conservative screening tool and the exposure estimates for both adults and children are well below 1% of the RfD, the Agency concludes that the potential for chronic dietary exposure through drinking water in insignificant.

3. *Non-dietary uses.* EPA has not estimated non-dietary exposure for pyridaben since there are no chronic or acute residential risks expected from the citrus, apple, pear and almond uses. The only other registered use is limited to commercial greenhouse for non-food ornamental plants. The potential for non-occupational exposure to the general population is, thus, not expected to be significant.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(V) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' While the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity in a meaningful way, EPA is commencing a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes the results of this pilot process will enable it to apply common mechanism issues to its pesticide risk assessments. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to risk assessments, and therefore believes that in most cases, there is no available information concerning mechanism that can be scientifically applied to tolerance decisions. Where it is clear that a particular pesticide may share a significant common mechanism with other chemicals, a tolerance decision may be affected by common mechanism issues. The Agency expects that most tolerance decisions will fall into the area in between, where EPA can not reasonably determine whether a pesticide does or does not share a common mechanism of toxicity with other chemicals (and, if so, how that common mechanism should be factored into a risk assessment). In such circumstances, the Agency will reach a tolerance decision based on the best, currently available and useable information, without regard to common mechanism issues. However, the Agency will also revisit such decisions when the Agency learns how to apply common mechanism information to pesticide risk assessments.

In the case of pyridaben, it is structurally similar to other members of the pyridazinone class of pesticides (i.e. pyrazon and norflurazon). However, since EPA has determined that it does not now have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment, this tolerance determination does not take into account common mechanism issues. The Agency will reexamine the tolerance for pyridaben, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

IV. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter-and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

In assessing the potential for risk to infants and children to residues of pyridaben, EPA considered data from oral developmental toxicity studies in the rat and rabbit, as well as data from

a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to the mothers. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Based on current data requirements, the database relative to pre-and post natal toxicity is complete. These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or post-natal sensitivity. Therefore, EPA concludes that reliable data support use of a hundredfold safety factor and an additional tenfold safety factor is not needed to protect the safety of infants and children. Therefore, no outstanding data requirements exist.

V. Determination of Safety for U.S. Population Including Infants and Children

1. *Chronic dietary exposure/risk.* A chronic dietary exposure/risk assessment was performed for pyridaben using a RfD of 0.005 mg/kg/day. Using the exposure assumptions previously described, and based on the completeness and reliability of the toxicity data base, EPA has concluded that aggregate exposure to pyridaben from its us on apples, pears, citrus and almonds will utilize 11.8 percent of the RfD for the general population and 74% for non-nursing infants < 1 year old which is the most exposed subpopulation. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose an appreciable risk to human health.

2. *Aggregate risks.* Based upon the available data and assumptions used for dietary and water exposure and risk estimates, the population group estimated to be the most highly exposed to pyridaben is non-nursing infants (< 1 year old), with a risk estimate from combined sources equaling 74 percent of the RfD. (Dietary exposure contributes 74% of the RfD and drinking water contributes less than 1% of the RfD). EPA therefore concludes that there is reasonable certainty that no harm will result to Consumers, including infants and children from aggregate exposure of pyridaben residues.

VI. Other Considerations

A. Endocrine Effects

No evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that pyridaben causes endocrine effects.

B. Metabolism in Plants and Animals

The metabolism of pyridaben in plants and animals is adequately understood for the purpose of this tolerance. There are no Codex maximum residue levels established for residues of pyridaben on the proposed commodities. There is a practical analytical method available for determination of residues of pyridaben. Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. As a condition of registration, EPA has requested that revisions and clarifications be made to the submitted methodology, and that the animal commodity method be improved. Once this method has been submitted, EPA will provide information on this method to FDA. In the interim, the analytical method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division, (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 703–305–5805.

VII. Summary of Findings

Tolerances are time limited to allow for development and review of additional residue field trials, long term storage stability studies, and revised analytical enforcement methodology. The analysis for pyridaben using anticipated residue levels shows that the proposed uses will not cause exposure to exceed the levels at which EPA believes there is an appreciable risk. All population subgroups examined by EPA are exposed to pyridaben residues at levels below 100 percent of the RfD for chronic effects. Based on the information and data considered, EPA concludes that the proposed time-limited tolerances will be safe. Therefore the tolerances are established as set forth in this document.

VIII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''Object'' to a tolerance regulation issued by EPA under the new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 15, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential

may be disclosed publicly by EPA without prior notice.

IX. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300492] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300492]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

X. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerance established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 7, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180— [AMENDED]

1. In part 180:

a. The statutory authority for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising § 180.494 to read as follows:

§ 180.494 Pyridaben; tolerance for residues.

(a) *General.* Time limited tolerances are established for residues of the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the following plants, and of the insecticide pyridaben and its metabolites (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2H)-one) and (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl)benzylthio]-chloropyridazin-3(2H)-one) on animals, as indicated in the following table. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Almonds	0.05	5/31/2001
Almond hulls	4.0	do.
Apple	0.6	do.
Apple pomace, wet	1.0	do.
Cattle, fat	0.05	do.
Cattle, meat	0.05	do.
Cattle, meat by-products	0.05	do.
Citrus	0.5	do.
Citrus oil	10.0	do.
Citrus pulp, dried	1.5	do.
Goat, fat	0.05	do.
Goat, meat	0.05	do.
Goat, meat by-products	0.05	do.
Hog, fat	0.05	do.
Hog, meat	0.05	do.
Hog, meat by-products	0.05	do.
Horse, fat	0.05	do.
Horse, meat	0.05	do.
Horse, meat by-products	0.05	do.
Milk	0.01	do.
Pears	0.75	do.
Sheep, fat	0.05	do.
Sheep, meat	0.05	do.
Sheep, meat by-products	0.05	do.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–12912 Filed 5–15–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300489; FRL–5717–5]

RIN 2070–AB78

Propamocarb Hydrochloride; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide propamocarb hydrochloride in or on the food commodities tomatoes, tomato puree, and tomato paste in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of propamocarb hydrochloride on